

# Kentucky Department for Medicaid Services

## Drug Review Options

The following chart lists the agenda items scheduled and the options submitted for review at the May 16, 2013 meeting of the Pharmacy and Therapeutics Advisory Committee.

Item	Options for Consideration
<p><b><u>New Products to Market:</u></b> <b><u>Kynamro™</u></b></p>	<p>Place this product non preferred in the PDL class titled Lipotropics, Other. Approval of mipomersen sodium will be granted as described below.</p> <ul style="list-style-type: none"> <li>• For initial treatment, approve for 6 months if ALL of the following are true: <ul style="list-style-type: none"> <li>○ Diagnoses of HoFH must be confirmed by the presence of at least one of the following: <ul style="list-style-type: none"> <li>▪ Documented DNA test for functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality; <b>OR</b></li> <li>▪ Skin fibroblast LDL receptor activity &lt;20% normal; <b>OR</b></li> <li>▪ Untreated total cholesterol (TC) &gt;500 mg/dL and triglycerides(TG) &lt;300 mg/dL and both parents with documented untreated TC &gt;250 mg/dL; <b>AND</b></li> </ul> </li> <li>○ Must be used as an adjunct to a low-fat diet supplying &lt; 20% of energy from fat; <b>AND</b></li> <li>○ Baseline alanine and aspartate aminotransferases (ALT, AST), alkaline phosphatase, and total bilirubin lab values must be obtained prior to initiating treatment; <b>AND</b></li> <li>○ Baseline low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) labs must be obtained prior to initiating treatment and required for renewal; <b>AND</b></li> <li>○ Patient tried and failed at least a 3 month trial of the maximally tolerated dose with two (2) of the following statins: simvastatin 40mg (Zocor), atorvastatin 80mg (Lipitor) OR rosuvastatin 40mg (Crestor), unless contraindicated; <b>AND</b></li> <li>○ Patient tried and failed at least a 3 month trial combination with both ezetimibe 10mg (Zetia) AND atorvastatin 80mg (Lipitor) OR simvastatin 40mg (Zocor), unless contraindicated; <b>AND</b></li> <li>○ Despite the pharmacological treatment with statins and ezetimibe, patient's LDL cholesterol <math>\geq</math> 300 mg/dL (or non-HDL cholesterol <math>\geq</math> 330 mg/dL).</li> </ul> </li> <li>• For continuation of treatment, approve for one year if ALL of the following are true: <ul style="list-style-type: none"> <li>○ Documented reduction of low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) from baseline; <b>AND</b></li> <li>○ Documentation of dosage adjustment if ALT or AST is <math>\geq</math> 3 times the upper limit of normal (ULN); <b>AND</b></li> <li>○ Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: elevations in transaminases (ALT, AST), hepatic steatosis, serious injection site reactions, and flu-like symptoms.</li> </ul> </li> </ul>

Item	Options for Consideration
<b><u>New Products to Market: Juxtapid™</u></b>	Place this product non preferred in the PDL class titled Lipotropics, Other; however, only approve Lomitapide (Juxtapid™) for a diagnosis of homozygous familial hypercholesterolemia if prescribed by a certified REMS approved provider with supporting documentation (signed attestation).
<b><u>New Products to Market: Nesina®</u></b>	Place this product non preferred with similar approval criteria and appropriate quantity limits in the PDL class titled DPP-4 Inhibitors.
<b><u>New Products to Market: Kazano®</u></b>	Place this product non preferred with similar approval criteria and appropriate quantity limits in the PDL class titled DPP-4 Inhibitors.
<b><u>New Products to Market: Oseni®</u></b>	Place this product non preferred with similar approval criteria and appropriate quantity limits in the PDL class titled DPP-4 Inhibitors.
<b><u>New Products to Market: Cometriq™</u></b>	Place this product non preferred with similar quantity limits in the PDL class titled Oral Oncology Agents.
<b><u>New Products to Market: Rescula®</u></b>	Place this product non preferred with appropriate quantity limits in the PDL class titled Prostaglandin Agonists.
<b><u>New Products to Market: Fulyzaq™</u></b>	<p>Place this product non preferred with appropriate quantity limits in the PDL class titled Antidiarrheals. Approval of crofelemer will be granted as described below.</p> <ul style="list-style-type: none"> <li>• For initial treatment, approve for 6 months if ALL of the following are true: <ul style="list-style-type: none"> <li>○ Patient has been diagnosed with human immunodeficiency virus; <b>AND</b></li> <li>○ Patient is experiencing diarrhea; <b>AND</b></li> <li>○ Plasma CD4 cell count indicates measure response to HAART; <b>AND</b></li> <li>○ Active infection has been ruled out via fecal collection and microbiologic culture; <b>AND</b></li> <li>○ Other secondary causes of diarrhea (eg, irritable bowel syndrome, gluten and lactose intolerance, traveler's diarrhea, functional diarrhea, and HAART associated diarrhea) have been ruled out by complete and appropriate physical and historical examination; <b>AND</b></li> <li>○ Patient has tried and failed the preferred antidiarrheals: loperamide, atropine-diphenoxylate</li> </ul> </li> <li>• For continuation of treatment, approve for one year if ALL of the following are true: <ul style="list-style-type: none"> <li>○ Documented reduction in the frequency and quantity of liquid stool volume for the previous 6 months; <b>AND</b></li> <li>○ Documented measured response to continued HAART; <b>AND</b></li> <li>○ Documented follow-up with patient that includes re-culture for microbiologic agents.</li> </ul> </li> </ul>
<b><u>Thiazolidinediones</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred.</li> <li>2. Continue quantity limits based on maximum recommended dose.</li> <li>3. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>4. For any new chemical entity in the Diabetes: Thiazolidinediones class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>

Item	Options for Consideration
<b><u>Glucocorticoids, Inhaled</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least three unique chemical entities should be preferred.</li> <li>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.</li> <li>3. Continue quantity limits on agents in this class.</li> <li>4. Continue to allow budesonide respules without PA for patients less than 8 years of age.</li> <li>5. For any new chemical entity in the Glucocorticoids, Inhaled class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Oral Steroids</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however at least generic formulations of budesonide, dexamethasone, methylprednisolone, prednisolone and prednisone should be preferred.</li> <li>2. The orally disintegrating formulation of prednisolone should be available for children &lt; 12 years of age.</li> <li>3. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>4. For any new chemical entity in the Oral Steroids class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Intranasal Steroids</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. Continue to maintain quantity limits based on maximum daily dose.</li> <li>4. For any new chemical entity in the Corticosteroids, Intranasal class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Intranasal Antihistamines</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Intranasal Antihistamines class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Topical Steroids</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one agent in each of the potency categories (low, medium, high and very high) should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Topical Steroids class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Topical Acne Agents</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least multiple generic formulations of benzoyl peroxide, one topical antibiotic agent for acne and tretinoin should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Topical Acne Agents class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>

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<u>Cytokine and CAM Antagonists and Related Agents</u>	<div>1. DMS to select preferred agent (s) based on economic evaluation; however, at least two self administrable products should be preferred.</div> <div>2. Agents not selected as preferred will be considered non preferred and require trial and failure of preferred product (s) with a FDA-approved indication for the requested diagnosis.</div> <div>3. All agents in the category should be approved for their FDA-approved indications only.</div> <div>4. Allow continuation of therapy for non preferred single-source branded products.</div> <div>5. Maintain quantity limits on agents within the category according to their maximum recommended dose, taking into consideration any escalating doses needed during initial therapy.</div> <div>6. For any new chemical entity in the Cytokine and CAM Antagonists and Related Agents class, require a PA until reviewed by the P&amp;T Advisory Committee.</div>																					
<u>Cytokine and CAM Antagonists and Related Agents Clinical Criteria</u>	<table><tr><th>Drug</th><th>Diagnosis</th><th>Prior Therapy</th></tr><tr><td rowspan="2">Orencia<sup>®</sup> (abatacept)</td><td>Rheumatoid arthritis</td><td>Trial and failure of 1 DMARD</td></tr><tr><td>Juvenile Idiopathic Arthritis (JIA)</td><td>Trial and failure of 1 DMARD</td></tr><tr><td rowspan="6">Humira<sup>®</sup> (adalimumab)</td><td>Rheumatoid Arthritis</td><td>Trial and failure of 1 DMARD</td></tr><tr><td>Juvenile Idiopathic Arthritis (JIA)</td><td>Trial and failure of 1 DMARD</td></tr><tr><td>Ankylosing Spondylitis</td><td>None</td></tr><tr><td>Plaque Psoriasis</td><td>Trial and failure of two of the following therapies:<ul style="list-style-type: none"><li>Methotrexate</li><li>Cyclosporine</li><li>Oral retinoid</li><li>Topical corticosteroids</li><li>Phototherapy/UV light</li><li>Coal tar preparations</li></ul></td></tr><tr><td>Crohn’s Disease</td><td>Failure of conventional therapy of at least one agent in at least 2 of the following classes (not all inclusive):<ul style="list-style-type: none"><li>5-ASA agents –examples: Mesalamine (Pentasa, Asacol, Rowasa)</li><li>Corticosteroids –examples: Cortenema, Prednisone</li><li>Immunosuppressives– examples: Azathioprine (Imuran), 6-Mercaptopurine (Purinethol)</li></ul></td></tr><tr><td>Psoriatic Arthritis</td><td>Trial and failure of one of the following treatment:</td></tr></table>	Drug	Diagnosis	Prior Therapy	Orencia <sup>®</sup> (abatacept)	Rheumatoid arthritis	Trial and failure of 1 DMARD	Juvenile Idiopathic Arthritis (JIA)	Trial and failure of 1 DMARD	Humira <sup>®</sup> (adalimumab)	Rheumatoid Arthritis	Trial and failure of 1 DMARD	Juvenile Idiopathic Arthritis (JIA)	Trial and failure of 1 DMARD	Ankylosing Spondylitis	None	Plaque Psoriasis	Trial and failure of two of the following therapies: <ul style="list-style-type: none"><li>Methotrexate</li><li>Cyclosporine</li><li>Oral retinoid</li><li>Topical corticosteroids</li><li>Phototherapy/UV light</li><li>Coal tar preparations</li></ul>	Crohn’s Disease	Failure of conventional therapy of at least one agent in at least 2 of the following classes (not all inclusive): <ul style="list-style-type: none"><li>5-ASA agents –examples: Mesalamine (Pentasa, Asacol, Rowasa)</li><li>Corticosteroids –examples: Cortenema, Prednisone</li><li>Immunosuppressives– examples: Azathioprine (Imuran), 6-Mercaptopurine (Purinethol)</li></ul>	Psoriatic Arthritis	Trial and failure of one of the following treatment:
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	Psoriatic Arthritis	Trial and failure of one of the following treatment:																				

			<ul style="list-style-type: none"> <li>• Oral NSAID</li> <li>• Methotrexate alone</li> <li>• Intra-articular corticosteroid</li> </ul>
		Ulcerative Colitis	Trial and failure of one of the following therapies: <ul style="list-style-type: none"> <li>• Corticosteroids</li> <li>• Immunosuppressant</li> </ul>
	Amevive <sup>®</sup> (alefacept)	Plaque Psoriasis	Trial and failure of two of the following therapies: <ul style="list-style-type: none"> <li>• Methotrexate</li> <li>• Cyclosporine</li> <li>• Oral retinoid</li> <li>• Topical corticosteroids</li> <li>• Phototherapy/UV light</li> <li>• Coal tar preparations</li> </ul>
	Kineret <sup>®</sup> (anakinra)	Rheumatoid Arthritis	Trial and failure of 1 DMARD
		Neonatal-Onset Multisystem Inflammatory Disease (NOMID)	None
	Cimzia <sup>®</sup> (certolizumab pegol)	Rheumatoid Arthritis	Trial and failure of 1 DMARD
		Crohn's Disease	Failure of conventional therapy of at least one agent in at least 2 of the following classes (not all inclusive): <ul style="list-style-type: none"> <li>• 5-ASA agents –examples: Mesalamine (Pentasa, Asacol, Rowasa)</li> <li>• Corticosteroids –examples: Cortenema, Prednisone</li> <li>• Immunosuppressives –examples: Azathioprine (Imuran), 6-Mercaptopurine (Purinethol)</li> </ul>
	Enbrel <sup>®</sup> (etanercept)	Rheumatoid Arthritis	Trial and failure of 1 DMARD
		Juvenile Idiopathic Arthritis (JIA)	Trial and failure of 1 DMARD
		Ankylosing Spondylitis	None
		Plaque Psoriasis	Trial and failure of two of the following therapies: <ul style="list-style-type: none"> <li>• Methotrexate</li> <li>• Cyclosporine</li> <li>• Oral retinoid</li> <li>• Topical corticosteroids</li> <li>• Phototherapy/UV light</li> </ul>

			<ul style="list-style-type: none"> <li>• Coal tar preparations</li> </ul>
		Psoriatic Arthritis	Trial and failure of one of the following treatment: <ul style="list-style-type: none"> <li>• Oral NSAID</li> <li>• Methotrexate alone</li> <li>• Intra-articular corticosteroid</li> </ul>
	Simponi™ (golimumab)	Rheumatoid Arthritis	Trial and failure of 1 DMARD
		Ankylosing Spondylitis	None
		Psoriatic Arthritis	Trial and failure of one of the following treatment: <ul style="list-style-type: none"> <li>• Oral NSAID</li> <li>• Methotrexate alone</li> <li>• Intra-articular corticosteroid</li> </ul>
	Remicade® (infliximab)	Rheumatoid Arthritis	Trial and failure of 1 DMARD
		Ankylosing Spondylitis	None
		Plaque Psoriasis	Trial and failure of two of the following therapies: <ul style="list-style-type: none"> <li>• Methotrexate</li> <li>• Cyclosporine</li> <li>• Oral retinoid</li> <li>• Topical corticosteroids</li> <li>• Phototherapy/UV light</li> <li>• Coal tar preparations</li> </ul>
		Crohn's Disease	Failure of conventional therapy of at least one agent in at least 2 of the following classes (not all inclusive): <ul style="list-style-type: none"> <li>• 5-ASA agents –examples: Mesalamine (Pentasa, Asacol, Rowasa)</li> <li>• Corticosteroids –examples: Cortenema, Prednisone</li> <li>• Immunosuppressives– examples: Azathioprine (Imuran), 6-Mercaptopurine (Purinethol)</li> </ul>
		Ulcerative Colitis	Trial and failure of one of the following treatments: <ul style="list-style-type: none"> <li>• Corticosteroid</li> <li>• Immunosuppressant</li> </ul>
		Fistulizing Crohn's Disease	None
		Psoriatic Arthritis	Trial and failure of one of the following treatment: <ul style="list-style-type: none"> <li>• Oral NSAID</li> </ul>

			<ul style="list-style-type: none"> <li>• Methotrexate alone</li> <li>• Intra-articular corticosteroid</li> </ul>
	Actemra® (tocilizumab)	Rheumatoid Arthritis	Trial and failure of 1 DMARD
		Juvenile Idiopathic Arthritis (JIA)	Trial and failure of 1 DMARD
	Xeljanz® (tofacitinib)	Rheumatoid Arthritis	Trial and failure of 1 DMARD
	Stelara™ (ustekinumab)	Plaque Psoriasis	Trial and failure of two of the following therapies: <ul style="list-style-type: none"> <li>• Methotrexate</li> <li>• Cyclosporine</li> <li>• Oral retinoid</li> <li>• Topical corticosteroids</li> <li>• Phototherapy/UV light</li> <li>• Coal tar preparations</li> </ul>
Non preferred products will require no less than a one month trial and failure of one preferred product which is approved for the same diagnosis.			
<b><u>Platelet Inhibitors</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least four unique chemical entities should be preferred. Based on the clinical merits, place in therapy and utilization of clopidogrel, it must be a preferred agent.</li> <li>2. Continue to allow ticagrelor products for use in patients with Acute Coronary Syndrome (ACS).</li> <li>3. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>4. For any new chemical entity in the Platelet Inhibitors class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>		
<b><u>Growth Hormone</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agents based upon economic evaluation; however, one preferred agent should be supplied in a pediatric convenient dosing form.</li> <li>2. Continue to require clinical PA for all agents, preferred or non-preferred.</li> <li>3. For any new chemical entity in the Growth Hormone class, require a PA until reviewed by the P &amp; T Advisory Committee.</li> </ol>		

Item	Options for Consideration
<p><b><u>Growth Hormone Clinical Criteria</u></b></p>	<p>Growth Hormones will be approved for one of the following diagnoses:</p> <ul style="list-style-type: none"> <li>• Growth Hormone Deficiency or Pituitary dwarfism</li> <li>• Pituitary disease from known causes such as pituitary tumor, pituitary surgical damage, hypothalamic disease, irradiation, or trauma such as Panhypopituitarism, Iatrogenic pituitary disorders. Other disorders of the pituitary and other syndromes of diencephalohypophyseal origin. Other disorders of the pituitary gland and craniopharyngeal duct</li> <li>• Turner's Syndrome</li> <li>• Chronic renal insufficiency &amp; end-stage renal disease (pre transplant)</li> <li>• Prader-Willi Syndrome</li> <li>• Idiopathic Short Stature (meaning of unknown origin). Also called non-growth hormone deficient short stature</li> <li>• Small for gestational age</li> <li>• Short Stature Homeobox Gene</li> <li>• Noonan Syndrome</li> <li>• HIV wasting or cachexia</li> <li>• Short bowel syndrome</li> </ul> <p>Non-preferred growth hormones require trial and failure of two preferred agents.</p>
<p><b><u>Narcotic Agonists/Antagonists</u></b></p>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Narcotic Agonist / Antagonists class, require PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<p><b><u>Fentanyl Buccal Products</u></b></p>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation.</li> <li>2. Require prior approval for all of these agents to ensure utilization based on FDA-approved indication.</li> <li>3. For any new chemical entity in the Narcotics: Fentanyl Buccal Products class, require PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<p><b><u>Fentanyl Buccal Products Clinical Criteria</u></b></p>	<p>Fentanyl Buccal products will be approved if ALL of the following are true:</p> <ul style="list-style-type: none"> <li>• Diagnosis of cancer pain; AND</li> <li>• Receiving and tolerant to opioid therapy, as evident by trial of opioid doses equal to, or greater than, morphine 60 mg daily or fentanyl patches 50 mcg/hr for at least one week without adequate pain control; AND</li> <li>• Unresponsive to therapy with three other immediate-released unique chemical entities utilized for breakthrough pain.</li> </ul>
<p><b><u>GI Antibiotics</u></b></p>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based upon economic evaluation; however, at least metronidazole, oral vancomycin, paromomycin and nitazoxanide should be preferred.</li> <li>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.</li> <li>3. For any new chemical entity in the GI Antibiotic class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>



Item	Options for Consideration
<b><u>1<sup>st</sup> Generation Cephalosporins</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent(s) based on economic evaluation; however, at least cephalexin should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the First Generation Cephalosporin class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>2<sup>nd</sup> Generation Cephalosporins</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent(s) based on economic evaluation; however, at least cefuroxime should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Second Generation Cephalosporin class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>3<sup>rd</sup> Generation Cephalosporins</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent(s) based on economic evaluation; however, at least cefixime and cefpodoxime should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Third Generation Cephalosporin class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Penicillins</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent(s) based on economic evaluation; however, at least amoxicillin, amoxicillin/clavulanate, ampicillin, dicloxacillin and penicillin V should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Penicillin class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Tetracyclines</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent(s) based on economic evaluation; however, at least generic formulations of doxycycline, minocycline, and tetracycline should be preferred.</li> <li>2. If demeclocycline is selected as non preferred, allow for its use in SIADH only.</li> <li>3. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>4. For any new chemical entity in the Tetracycline class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Ketolides</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent(s) based on economic evaluation.</li> <li>2. Maintain prior authorization criteria for telithromycin to ensure this product is being used for multi-drug resistant infections only.</li> <li>3. Continue current quantity limit (10 days supply per month).</li> <li>4. For any new chemical entity in the Antibiotics: Ketolide class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>

Item	Options for Consideration
<p><b><u>Ketek® Clinical Criteria</u></b></p>	<p>Telithromycin (Ketek®) should be approved for a diagnosis of community-acquired pneumonia (CAP) IF:</p> <ul style="list-style-type: none"> <li>• There has been previous use (within the past 28 days) of <b>ONE</b> of the following: <ul style="list-style-type: none"> <li>○ Penicillin (e.g., amoxicillin, amoxicillin-clavulanate, ampicillin-sulbactam, or piperacillin-tazobactam); OR</li> <li>○ 2nd or 3rd generation cephalosporins (e.g., cefuroxime, cefpodoxime, cefprozil, cefotaxime, ceftriaxone); OR</li> <li>○ Macrolide (e.g., azithromycin, clarithromycin, erythromycin); OR</li> <li>○ Fluoroquinolone (e.g., levofloxacin, gatifloxacin, moxifloxacin) ; OR</li> <li>○ Tetracycline (e.g., doxycycline); OR</li> <li>○ Trimethoprim/sulfamethoxazole (e.g., Bactrim); AND</li> </ul> </li> <li>• Request is <b>NOT</b> for more than a 10-day supply</li> </ul> <p><b>**If Ketek was initiated in the hospital, approve to complete the course of antibiotic therapy</b></p>
<p><b><u>Macrolides</u></b></p>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent(s) based on economic evaluation; however, at least three unique chemical entities should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Antibiotics: Macrolides class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<p><b><u>Oxazolidinones</u></b></p>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent(s) based on economic evaluation; however, at least linezolid should be preferred.</li> <li>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.</li> <li>3. Continue appropriate quantity limits.</li> <li>4. For any new chemical entity in the Oxazolidinones class, require a PA and quantity limit until reviewed by the P&amp;T Advisory Committee.</li> </ol>

Item	Options for Consideration
<p><b><u>Zyvox®</u></b> <b><u>Clinical</u></b> <b><u>Criteria</u></b></p>	<p>Diagnoses to approve:</p> <ul style="list-style-type: none"> <li>• Vancomycin-Resistant Gram Positive Infections (VRE) via current culture and sensitivity testing for <i>Enterococcus faecium</i> or <i>Enterococcus faecalis</i></li> <li>• Methicillin-Resistant <i>S. aureus</i> Infections (MRSA) via current culture and sensitivity testing</li> <li>• Empiric management of suspected MRSA infection without culture confirmation if any of the following are true:             <ul style="list-style-type: none"> <li>○ Previously documented MRSA infection; OR</li> <li>○ Previous cellulitis caused by documented MRSA; OR</li> <li>○ Skin and soft tissue infection with abscess; OR</li> <li>○ Patient has:                 <ul style="list-style-type: none"> <li>▪ Failed antibiotic therapy within the past month with any of the following:                     <ul style="list-style-type: none"> <li>• Tetracycline, or</li> <li>• Sulfamethoxazole/trimethoprim, or</li> <li>• Fluoroquinolone, or</li> <li>• Clindamycin; AND</li> </ul> </li> <li>▪ Presents with any of the following risk factors:                     <ul style="list-style-type: none"> <li>• Health facility stay/visit (current or within the past month); or</li> <li>• Surgery in the past month; or</li> <li>• Participation in team sports (current or past month); or</li> <li>• Jail/Prison (current or in past month); or</li> <li>• Military (current or in past month); or</li> <li>• History of “spider bite” within the past month; or</li> <li>• Pediatrics enrolled in daycare or school (current or in past month); or</li> <li>• Multiple areas of induration; or</li> <li>• HIV; or</li> <li>• Permanent indwelling catheters; or</li> <li>• Percutaneous implanted device; or</li> <li>• Previously colonized with multi-drug resistant pathogens including MRSA; or</li> <li>• Diabetic foot ulcer; or</li> <li>• End stage renal disease.</li> </ul> </li> </ul> </li> </ul> </li> </ul>